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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/496,893	BROWN, STEPHEN J.	
	Examiner	Art Unit	
	Carolyn Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *83,85,86,88-90,92-94 and 96-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83,85,86,88-90,92-94 and 96-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 11/22/10, are acknowledged. Amended claims 83, 90, and 94 and cancelled claims 1-82, 84, 87, 91, and 95 are acknowledged.

Applicant's arguments, filed 11/22/10, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 83, 85-86, 88-90, 92-94, and 96-103 are herein under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 83, 85-86, 88-90, 92-94, and 96-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lapointe et al. (US 6,678,669) in view of Portwood et al. (US 5,950,630) and Altman et al. (5,572,421). This rejection is necessitated by amendment.

Lapointe et al. describe a method and system for identifying new markers for disease to design new tests and improve the sensitivity and specificity of tests as well as medical diagnostic tests that generate groups of individuals useful in researching disease influence in individuals (abstract; col. 1, last paragraph to col. 2, first paragraph; col. 3, last two paragraphs to col. 4, first paragraph; col. 5, last paragraph to col. 6, last paragraph; col. 20, third paragraph; claim 38) which represents a method and system for generating/identifying groups of individuals useful in researching influence of a disease (as stated in the preambles of instant claims 83, 90, 94). Lapointe et al. describe collecting observation by examining and querying a group of test patients in whom the medical condition is known (claim 38; col. 6, fourth paragraph) which represents selecting individuals having a risk factor for a disease, as stated in instant claim 83. Lapointe et al. describe the method and system are computer-based with a consensus of networks and several processors involving input interface screen and inputting patient information (claims 1, 3; col. 2, first paragraph; col. 6, fourth paragraph; col. 9, second paragraph; col. 10, lines 60-62; col. 84, second to third paragraph; Figure 11), as well as a computer connectable with a monitoring device that monitor pulse rate or blood pressure (col. 11, seventh paragraph; col. 12, seventh paragraph; col. 15, seventh paragraph) with the system adapting to the particular environment (col. 6, last paragraph) which represents providing a communications apparatus (as stated in instant claim 83, 90), a communication network (as stated in instant claims 90, 94), a communication apparatus connectable with a monitoring device (as stated in instant claim 88, 94) involving blood pressure and pulse rate (as stated in instant claims 89, 94, 96). Lapointe et al. describe sending queries to each individual, for example "Do you smoke?" and “How many packs per day do you smoke?”, supplied in a computer-readable form to a system operating on a

computer (instant claims 3, 38, 167; col. 15, seventh paragraph; col. 30, line 35 to col.) and using a computer script program (col. 89-239; Figures 11 and 13) which represents presenting queries to each individual through an apparatus (as stated in instant claim 83, 94) and script-based queries (as stated in instant claim 90), a computer program (as stated in instant claim 85), and queries related to behavior as well as communicate environmental information (i.e. smoking environment) (as stated in instant claims101-103). Lapointe et al. describe answers to questions, collecting input data/responses communicating information about the individuals, storing patient data/responses in a database and further train systems to develop systems that are adapted to a particular genetic population, inputting additional data (claims 38, 116, 167, 212; col. 6, fourth and last paragraphs; col. 9, second paragraph; col. 32, second paragraph) which represents receiving and storing responses of each individual, as stated in instant claims 83, 90. Lapointe et al. describe categorizing observations and defining similar groups, categorizing responses from patient historical questionnaires, and categorizing women into different classes (claims 38, 52; Figure 4; col. 30, lines 45-46; col. 14, fifth paragraph; col. 15, fourth and fifth paragraphs) and categorizing individuals via identifying the disease state or condition of a patient as well as adapting systems for a particular genetic population (claim 38, col. 6, second and last paragraphs) and diabetes (col. 9, third paragraph) which represents defining a plurality of groups including phenotypic classifications. Lapointe et al. describe before, during or after collecting observations from a group of test patients, performing biochemical tests on at least one test patient and categorizing them into a set of candidate variables and providing biochemical test results for all or a subset of patients for whom the patient data are known with biochemical tests including bioassays and collecting genetic history of a patient and using genetic algorithms

(claims 60, 116; col. 22, second paragraph; col. 25, fourth paragraph) using a genetic algorithm and NeuroGenetic Optimizer and Knowledge discovery in data (KDD) which identifies relationships among variables as well as identifying variables and sets thereof ranking variables and finding correlations (col. 13, last paragraph; col. 7, third paragraph to col. 8, first paragraph; col. 18, lines 17-67; col. 20, third and fifth paragraphs; col. 22, second paragraph), which represents receiving and comparing genotype information, as stated in instant claims 83, 90, 92, 94, 97. Lapointe et al. describe developing systems for a particular genetic population, identifying subsets of relevant variables and outputting information (col. 6, fourth to sixth paragraphs; col. 8, second paragraph; col. 13, third paragraph; col. 27, third paragraph; claims 37, 38, 60, 116) including determining relationships and differences between variables (col. 17, second paragraph to col. 18, last paragraph; col. 29, second paragraph to col. 42, line 35; col. 49, fourth paragraph to col. 56, line 50; col. 83, second paragraph to col. 88, last paragraph) which represents generating a report that represents a subset of genotype information associated with each group wherein differences in said genotype information between said groups is expressed in terms of phenotypic classifications, as stated in instant claims 83, 90, 94. Lapointe et al. describe categorizing individuals via identifying the disease state or condition of a patient as well as adapting systems for a particular genetic population (claim 38, col. 6, second and last paragraphs) and diabetes (col. 9, third paragraph) which represents categorizing individuals into groups by risk factor or disease progression including diabetes, as stated in instant claims 86, 90, 92, 93, 94, 97, 98, 99, 100, 101, 102. Lapointe et al. do not describe transmitting a computer program containing queries and predefined response choices to a communication apparatus, wherein the program causes the apparatus to present queries and predefined response choices and

collect responses to said queries (instant claim 83), a server transmitting a computer program containing queries and predefined response choices to a communication apparatus, the program causing the apparatus to present queries to the individual and collect responses (instant claims 90 and 94).

Portwood et al. describe utilizing computer and electronic communication systems that transmits a computer program (i.e. communication software program) containing queries to a communication apparatus, wherein the program causes the apparatus to present queries and collect responses to said queries as well as a server (Figures 1, 2 [data flow to and from patient], 3, 4 (1108); col. 5, second to fourth paragraphs[two-way pager and other two-way communication systems permitting patient to confirm receipt of message and respond to queries]; col. 6, third and fourth paragraphs; col. 7, lines 20-26 [responses to messages are received from patient]; col. 7, lines 35-51 [various software subroutines]; col. 8, last paragraph to col. 9, fourth paragraph [message to query patient on health matters, to receive an updated status of health and effectiveness or problems of prescribed medical regimen]; col. 16, last 2 paragraphs to col. 17, second paragraph). Portwood et al. do not describe predefined response choices.

Altman et al. describe a hand-held medical questionnaire presentation device used by a patient for displaying questions to a patient and a limited number of keys by which the patient can enter answers, including predefined response choices (i.e. yes, no buttons) which are then stored in a memory device (abstract; col. 4, eighth paragraph; col. 6, seventh paragraph; Figures 1-4). Altman et al. describe using programs for uploading and downloading subroutines including asking questions and recording answers (col. 6, sixth paragraph; col. 11, Figures 5, 6,

7, 13) and the patient's responses can be transmitted to a computerized medical record-keeping or management system that is being used by the patient's physician or hospital, such as a computerized workstation which can be coupled to a larger system (i.e. a mainframe computer or network connection) including remote connections (Figure 4; col. 8, fourth sixth paragraphs).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to transmit a computer program containing queries to a communication apparatus and collect responses as taught by Portwood et al. in the method and system of Lapointe et al. wherein the motivation would have been to monitor medication usage as well as patient wellness permitting the patient contact regardless of where the patient may be located at that moment, as stated by Portwood et al. (col. 1, fourth paragraph and last paragraph to col. 2, first paragraph). It would have been further obvious to use a hand-held medical questionnaire device with predefined response choices as taught by Altman et al. in the method and system of Lapointe et al. and Portwood et al. wherein the motivation would have been to automate data collection and calculations to produce numerical measures of a patient's health risk, surgical risk, capacity to function in daily life and permit easy comparisons of performance or medical condition with other patients, as stated by Altman et al. (col. 1, third paragraph and col. 2, fourth paragraph to seventh paragraph).

Thus, Lapointe et al. in view of Portwood et al. and Altman et al. make obvious the instant invention.

Applicant summarizes Lapointe et al., Portwood et al., and the instant invention. Applicant argues that Lapointe et al. and Portwood et al. do not describe the transmitting and receiving responses limitations in instant claim 83. This statement is found unpersuasive as Portwood et al. describe utilizing computer and electronic communication systems that transmits a computer program (i.e. communication software program) containing queries to a communication apparatus, wherein the program causes the apparatus to present queries and collect responses to said queries as well as a server (Figures 1, 2 [data flow to and from patient], 3, 4 (1108); col. 5, second to fourth paragraphs[two-way pager and other two-way communication systems permitting patient to confirm receipt of message and respond to queries]; col. 6, third and fourth paragraphs; col. 7, lines 20-26 [responses to messages are received from patient]; col. 7, lines 35-51 [various software subroutines]; col. 8, last paragraph to col. 9, fourth paragraph [message to query patient on health matters, to receive an updated status of health and effectiveness or problems of prescribed medical regimen]; col. 16, last 2 paragraphs to col. 17, second paragraph). In addition, Altman et al. describe a hand-held medical questionnaire presentation device used by a patient for displaying questions to a patient and a limited number of keys by which the patient can enter answers, including predefined response choices (i.e. yes, no buttons) which are then stored in a memory device (abstract; col. 4, eighth paragraph; col. 6, seventh paragraph; Figures 1-4). Altman et al. describe using programs for uploading and downloading subroutines including asking questions and recording answers (col. 6, sixth paragraph; col. 11, Figures 5, 6, 7, 13) and the patient's responses can be transmitted to a computerized medical record-keeping or management system that is being used by the patient's physician or hospital, such as a computerized workstation which can be coupled to a larger

system (i.e. a mainframe computer or network connection) including remote connections (Figure 4; col. 8, fourth sixth paragraphs). Applicant's arguments are deemed unpersuasive for the reasons given above.

Other prior art

Although not being used as prior art, the following reference has been made of record: Herren et al. (US 6,108, 635) disclose a method and integrated disease information system with an interface involving querying, receiving user input of biological parameters, projecting disease progression outcomes taking risk factors into account for various groups, and analyzing for each group of patient types based on standard categories of factors.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. If you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, please call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

January 20, 2011

/Carolyn Smith/
Primary Examiner
AU 1631